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y ONCOLOGY SYSTEMS LIMITED

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Department of Health and Human Services
Centre of Device and Radiological Health
Office of Device Evaluation
Traditional 510(k) section

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by section 21 CFR 807.92

Date: November 13th , 2012

Submitter of 510(k):

Company name:	Oncology Systems Ltd.
510k number:	K123357
Address:	14 Longbow Professional Centre, Longbow Close SHREWSBURY SHROPSHIRE SY1 3GZ UNITED KINGDOM
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Correspondent:	Carl Walker Service and Quality Manager

Device Name:

Trade/Proprietary Name:	OnQ rts®
Common/Usual Name:	RTS Imaging Software
Classification	Class II
Classification Name:	Medical charged-particle radiation therapy system. (21 CFR 892.5050 Product Code: MUJ) Picture Archiving and communications system (21 CFR 892.2050, Product Code LLZ)

Legally Marketed Device(s)
Our modified device is based on the legally marketed device cited in the table below:

Manufacturer	Device	510(k) #
MIM Software Inc	Mobile MIM	K103785
MIM Software Inc	Mobile MIM (RT)	K112930

Device description:
OnQ rts® is a stand-alone medical imaging software program that imports DICOM images from different modalities and provides imaging tools to visualise, compare, contour, co-register medical images, anatomical structures and radiation therapy dose distributions. These procedures are performed by manual, semi-automatic or automatic techniques which extract anatomical information for image contouring and analysis from the DICOM data. The system can operate as a single workstation or with multiple workstations, with one of them being the server networked with multiple clients and remotely via Citrix® terminal services. OnQ rts is not intended for use with hand-held mobile devices

OnQ rts software includes the import and export of DICOM data securely via a network connection. The imported images, from different modalities, are processed to provide a clinical picture of the anatomy and corresponding radiation therapy doses. OnQ rts co-registers images together, using rigid image registration (RIR) and elastic/deformable image registration (DIR) or a combination of both. These images can display imported or generated contours (anatomical and dose) overlaid onto the fused images.

OnQ rts contouring can be performed manually or automatically from a library of user defined or prepared pre-contoured CT cases. The library atlas files act as a template that is then mapped to the patients' anatomy. The contours are reviewed and approved before export, e.g. to radiotherapy planning software. OnQ rts can import radiation therapy treatment planning data (dose and dose distributions) which can then be displayed for review, radiation therapy dose comparison and analysis. The software provides contour comparison tools using a range of comparison metrics that highlight variations between VOIs in terms of size, shape and location. OnQ rts is not a radiation therapy treatment planning system and can only display and evaluate dose plan information generated from radiation therapy equipment.

Intended use:

OnQ rts software is stand-alone software that provides a means of visualizing and comparing medical image data from multiple DICOM compliant imaging modality devices. It is used for the display, evaluation, co-registration and fusion of medical images, contour of anatomical structures and radiation therapy dose distributions to aid in radiation therapy planning, diagnostic radiology, oncology and other medical specialties. Note: the software is not for use with digital mammography.

Summary of the Technical Characteristics
OnQ rts and the predicate devices have the same technical characteristics which include a software product that imports DICOM images and data for registration, display, evaluation and analysis. This data includes different modality images, contours and radiation dose information. These similarities in design and technology are the basis and reason for substantial equivalence of OnQ rts to the legally marketed predicate devices.

Summary of Non- clinical testing
Test Plans were written and executed internally which validate that OnQ rts meets the product requirements. The product requirements include equivalent features and technical characteristics as the predicate device and the test results confirmed that OnQ rts is substantially equivalent to the predicate device. This submission includes the comprehensive system test plan, the pass/fail results and a summary of test results. These results concluded that the software performed appropriately and the testing included confirmation of image fusion, atlas based segmentation, auto contouring, 4D contouring, analysis tools (DVH), adaptive re-

planning (dose mapping), integration and display of radiation therapy doses. The same features and technical characteristics are demonstrated in the legally marketed predicate device. This concludes that OnQ rts is as safe, as effective and performs as well or better than the predicate device.

Summary of Clinical testing
Clinical testing was not required to demonstrate substantial equivalence.

Conclusion
Based on the defined technical characteristics and the non-clinical testing that was performed it is determined that OnQ rts is as safe, as effective and performs as well or better than the predicate device and is therefore substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Ms. Lu Anne Johnson
c/o Capamed, Inc.
Oncology Systems Limited
1917 29 3/4 Ave
RICE LAKE WI 54868

December 28, 2012

Re: K123357
Trade/Device Name: OnQ rts
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ, LLZ
Dated: October 24, 2012
Received: October 31, 2012

Dear Ms. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123357

Device Name: OnQ rts

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Note: The software is not for use with digital mammography

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123357